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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,145	08/04/2003	Chew Kiat Heng	NAA 0018 PA/41049.20	5097
23368	7590	11/17/2006	EXAMINER	
DINSMORE & SHOHL LLP ONE DAYTON CENTRE, ONE SOUTH MAIN STREET SUITE 1300 DAYTON, OH 45402-2023			WHALEY, PABLO S	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/634,145	HENG ET AL.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 1-15 and 17-27. This application contains claims 16 and 17 drawn to an invention nonelected with traverse in the response filed 01/31/2006. Applicant's arguments that claim 17 should be examined as it recites both "genetic" and "non-genetic factors" is persuasive.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied, as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

### *INFORMATION DISCLOSURE STATEMENT*

A legible copy of Schaefer et al. has been received, and therefore the information disclosure statement filed 2/13/2004 has been considered in full.

**CLAIM REJECTIONS - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Applicant's arguments, filed 08/28/2006, that claims 1-15, 17, 18, 19, and 21-27 now recite a concrete, tangible, and useful result is not deemed to be persuasive. This rejection is maintained for the reasons set forth below.

Claims 1-15, 17-20, and 22-27 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. A statutory process must include a step of a physical transformation of matter, or produce a concrete, tangible, and useful result [State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998)], [AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999))].

Claims 1-15, 17-19, and 22-26 are directed to a method of determining a statistical model for predicting disease risk, comprising steps that do not include a physical transformation of matter. Claim 27 is directed to a method of weighing a plurality of data sets, however the Examiner maintains that this claim also comprises steps that do not include a physical transformation of matter. Furthermore, reading the claims in light of the specification, the claimed method steps are not limited to physical steps (i.e. done by a user). Therefore, the instant claims encompass non-physical (i.e. in-silico) method steps which do not result in a physical transformation of matter. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful result (i.e. a specific and substantial). In the instant case, the claimed method does not recite a tangible result such that it is useful to one skilled in the art. For these reasons, the instant claims are not statutory. This

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rejection could be overcome by amending the claims to recite a result that is "displayed" or "outputted" (e.g. output to a user, a display, a memory, etc.), or by amending the claims to include a step of a physical transformation of matter.

Claim 20 is directed to a system. However, the Examiner would like to clarify that the claimed system is not limited to comprise any hardware element or combination of software and hardware such that it is interpreted to be a physical article of manufacture. For the reasons set forth above, the claims are not statutory. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter at 1300 OG 142, Annex IV, Nov. 22, 2005. Also see the updated version of the MPEP Section 2106 that is available online (<http://www.uspto.gov/web/offices/pac/mpep/mpep.htm>).

### ***NEW MATTER***

Claims 1-15 and 17-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claim 1 has been amended to recite the limitation "choosing said candidate model with said parameters so optimized as a risk model...to particular member" (step d, lines 2-6) in the response filed 08/28/2006. However, the above limitation directed to "choosing said candidate

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model" do not appear to be taught in the specification and are not present within the scope of the original claims as filed.

Claim 21 has been amended to recite the limitation "storing said candidate model with said parameters so optimized as a risk model...to particular member" (step d, lines 2-6) in the response filed 08/28/2006. However, the above limitation directed to "storing" said candidate model do not appear to be taught in the specification and are not present within the scope of the original claims as filed. As the newly recited limitations are not supported by the originally filed claims or disclosure, the claims are rejected for reciting new matter. This rejection is necessitated by amendment.

#### **CLAIM REJECTIONS - 35 USC § 112, 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 and 17-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 21 recite the limitation "parameters so optimized as a risk model" (step d, lines 2-6). It is unclear in what way said parameters are "so optimized as a risk model." Clarification is requested. This rejection is necessitated by amendment.

Claim 13 recites "indicative of the representativeness". The Examiner maintains that it is unclear as to the applicant's intended meaning of "representativeness." In the claimed context, it is unclear in what way an adjustment factor is "indicative of the representativeness of the

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member." Clarification is requested. Claims 2-12 and 21-26 are rejected as they depend either directly or indirectly from claims 1 and 21. Claims 14-18 and 20 are rejected as they depend either directly or indirectly from claim 13.

### **CLAIM REJECTIONS - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 8-11, 13, and 19-21 are rejected under 35 U.S.C. 102 (b) as being anticipated by Schoonjans (MedCalc, [www.medcalc.be/manual/cox-regression.php](http://www.medcalc.be/manual/cox-regression.php) , Copyright 1993, p.1-6).

Applicant's arguments, filed 08/28/2006, that Schoonjans does not teach: (i) determining weights associated with collected data sets used in estimation of "b" by Cox regression, have been fully considered but are not persuasive for the following reasons:

Regarding (i): As set forth in the previous office action, Schoonjans teaches a statistical method and software package for modeling a hazard. More specifically, Schoonjans teaches a collection of predictor variables  $X_1, \dots, X_k$ , which the Examiner has reasonably interpreted as model parameters associated with data sets in a population, as in claim 1. Furthermore, as each

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of said parameters are "weighted" according to the coefficient " $b_i$ " in the form " $b_i X_i$ ", the Examiner has reasonably interpreted "weights" to be associated with a plurality of data sets, as in claim 1. Furthermore, Schoonjans teach the selection of an optimized hazard model data for fitting data and displaying "survival curves" [p.6], as in amended claims 1 and 21 [step d]. Schoonjans also teaches the input of "survival data", which has been interpreted as non-genetic data as in claim 2. Therefore, for the reasons set forth above and in the previous office action, the Examiner maintains that Schoonjans indeed teaches all of the limitations of claims 1, 2, 3, 8-11, 13, and 19-21.

Claims 1, 2, 4, and 10 are rejected under 35 U.S.C. 102 (b) as being anticipated by Fisher et al. (Annu. Rev. Public Health, 1999, 20, p.145-157).

The Examiner would like to clarify for the record that "Lloyd et al." should have recited "Fisher et al." as the Examiner inadvertently used the author's first name instead of the last name (i.e. Lloyd D. Fisher). This reference is therefore clarified above. Applicant's arguments, filed 08/28/2006, that Fisher et al. do not teach: (i) determining weights associated with collected data sets used in estimation of "b" by Cox regression have been fully considered but are not persuasive for the following reasons:

Regarding (i): As set forth in the previous office action, Fisher et al. teach methods using time-dependent covariates in the Cox proportional-hazards regression model [Abstract]. More specifically, Fisher et al. teach prediction of risk using weighted averages [p.148, ¶ 2], weights to predict diagnosis in a population [p.151, ¶ 2], and weighted scoring functions [p.156], as in claim 1. Therefore the Examiner has reasonably interpreted "weights" to be associated with a



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plurality of data sets, as in claim 1. Therefore, for the reasons set forth above and in the previous office action, the Examiner maintains that Fisher et al. indeed teaches all of the limitations of claims 1, 2, 4, and 10.

### CONCLUSION

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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11/12/06